

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

**DUKE UNIVERSITY, ALLERGAN, INC., and
ALLERGAN SALES, LLC.**

Plaintiffs,

Civil Action No. 3:18-cv-14035 BRM-TJB

v.

**AKORN INC., and HI-TECH PHARMACAL
CO., INC.,**

Defendants.

STIPULATION AND [REDACTED] ORDER

The Court, upon the consent and request of Plaintiffs Duke University, Allergan, Inc. and Allergan Sales, LLC (collectively, “Plaintiffs”), and Defendants Akorn, Inc. and Hi-Tech Pharmacal Co., Inc. (collectively, “Akorn”), hereby acknowledge the following Stipulation and issues the following Order.

STIPULATION

1. This Court has subject matter jurisdiction over the above-captioned patent infringement action (the “Action”) and personal jurisdiction over Plaintiffs and Akorn for purposes of the Action. Venue is proper in this Court as to Plaintiffs and Akorn for purposes of the Action.

2. In the Action, Plaintiffs have asserted claims against Akorn for infringement of U.S. Patent No 9,579,270 (the “Patent in Suit”) in connection with Akorn’s submission of Abbreviated New Drug Application (“ANDA”) 203051 directed to a generic bimatoprost ophthalmic solution, 0.03% product to the U.S. Food and Drug Administration (“FDA”).

3. For purposes of the Action, Akorn admits that submission of ANDA 203051 to the FDA for the purpose of obtaining regulatory approval to engage in the commercial manufacture,

use, and/or sale of a generic bimatoprost ophthalmic solution, 0.03% product within the United States before the expiration of the Patent in Suit was an act of infringement of the Patent in Suit under 35 U.S.C. § 271(e)(2)(A).

4. By this Stipulation and Order, the Parties agree that all other claims, defenses, counterclaims set forth in the pleadings in the Action, including allegations and averments contained therein, should be dismissed, without prejudice.

ORDER

Accordingly, pursuant to the above Stipulation, and upon the consent and request of Plaintiffs and Akorn, **IT IS HEREBY ORDERED, ADJUDGED AND DECREED THAT:**

1. The filing of ANDA No. 203051 was a technical act of infringement of the Patent in Suit under 35 U.S.C. § 271(e)(2)(A). No decision in the Action has been obtained by either party regarding the validity of the Patent in Suit and/or whether any commercial making, using, selling, or offering to sell within the United States, or importing into the United States, of the Akorn ANDA Product described by ANDA No. 203051 would infringe the Patent in Suit.

2. All other claims, defenses, and counterclaims set forth in Plaintiffs' and Akorn's pleadings against each other in the Action, including the allegations and averments contained therein, are hereby dismissed, without prejudice.

3. Absent a license or other authorization by Plaintiffs, Akorn, its officers, agents, servants, employees, and attorneys, and all other persons in active concert or participation with any of them who receive actual notice of this Order by personal service or otherwise, are hereby enjoined from manufacturing, using, offering to sell, or selling within the United States, or importing into the United States, the generic bimatoprost ophthalmic solution, 0.03% product that is the subject of ANDA 203051 or any other ANDA that references New Drug Application 22-

369 and for which LATISSE® is the reference listed drug during the life of the Patent in Suit, including any extensions and pediatric exclusivities unless and until all then-asserted claim(s) of the Patent in Suit are found invalid or unenforceable by a court decision from which no appeal has been or can be taken.

4. Plaintiffs and Akorn each expressly waive any right to appeal or otherwise move for relief from this Stipulation And Order.

5. This Court retains jurisdiction over Plaintiffs and Akorn for purposes of enforcing this Stipulation And Order.

6. This Stipulation And Order shall finally resolve the Action between Plaintiffs and Akorn.

7. Nothing herein prohibits or is intended to prohibit Akorn from maintaining a “Paragraph IV Certification” pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) or pursuant to 21 C.F.R. § 314.94(a)(12) with respect to the Patent in Suit.

8. The Clerk of the Court is directed to enter this Stipulation And Order in the above-captioned Action forthwith.

SO ORDERED:

This 15th day of October, 2019



HONORABLE BRIAN MARTINOTTI
UNITED STATES DISTRICT JUDGE

Date: October 14, 2019

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